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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/478,737	01/06/2000	Patricia D. Wilson	A3275970165.0555	2081

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BAKER & BOTTS  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/11/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/478,737

Applicant(s)

WILSON ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-29, 31-36 is/are allowed.
- 6) ☒ Claim(s) 21-23, 25, 26, 28 and 32 is/are rejected.
- 7) ☒ Claim(s) 30, 37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Formal Matters***

Claims 21, 23, 24, 27, 29, 31, 33 were amended in Paper No. 11, 11/27/2002. Claims 21-37 are pending and under consideration.

### ***Claim Objections***

Claims 30 and 37 stand objected to because of the following informalities: They are dependent on cancelled claims. Appropriate correction is required.

### ***Response to Amendment***

The rejection of claims 21-37 under 35 USC § 112 first paragraph for scope of enablement, has been withdrawn.

The rejection of claims 21-37 under 35 USC § 112 first paragraph as lacking written description, has been withdrawn.

The rejection of claims 21, 24, 27, 29, 31, 33 under 35 USC § 112 second paragraph has been obviated by Applicant's amendment, and is thus withdrawn.

### ***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "over expressed" in claim 26 is a relative term which renders the claim indefinite. The term " over expressed " is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the metes and bounds of the invention.

Applicant argues that this rejection is overcome because the claim has been amended. However, this claim was not amended in Paper No. 11, 11/13/2002, and the rejection is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (1996) in view of Van Adelsberg (1999).

Wilson teaches the correlation between PKD-1 content and degree of adherence to type I collagen. Van Adelsberg teaches peptide inhibitors derived from the PKD repeats of polycystin-1 (page 301, Figure 1). It would have been obvious to one of skill in the art at the time the invention was made to measure adherence of polycystin-1 expressing cells to collagen type-1 in the presence of the inhibitory peptides derived from the PKD repeats of polycystin-1 as taught by Van Adlesberg, with a reasonable expectation of success. One of skill in the art at the time the invention was made would have been motivated to make this modification to determine if type I collagen is a ligand for polycystin-1.

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Applicant argues that the Van Adelsberg reference fails to teach mutant phenotypes associated with expression of mutant PKD-1 and that the Wilson reference does not teach screening methods for identification of compounds capable of modulating PKD-1 activity. In response, claims 21 and 23 of the instant application do not contain a limitation whereby the polycystin-1 used in the assay is a mutant polycystin-1, while claim 22 is drawn to screening methods using mutant polycystin-1. The Van Adelsberg reference teaches methods of measuring the effects of peptides derived from PKD-1 extracellular domain on polycystin-1 function, and screening those peptides for effect on ureteric bud branching morphogenesis. The Van Adelsberg reference further teaches that mutations in the PKD1 gene are responsible for about 85% of autosomal dominant polycystic kidney disease (Van Adelsberg page 299, column 1, first paragraph). The Wilson reference also teaches that mutations in the PKD-1 gene causes autosomal dominant polycystic kidney disease, and further teaches assays to measure adherence of cells comprising PKD-1 to collagen type I, including assays using ADPKD epithelia which comprise mutant PKD-1. Given the screening method of Van Adelsberg, and the teaching of Wilson on measuring the adherence of PKD-1, including mutant PKD-1, to type I collagen, the combination of Van Adelsberg and Wilson references render it obvious to practice a method of identifying compounds which modulate polycystin-1, and mutant polycystin-1, mediated increase in adherence to Type I collagen.

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***Conclusion***

Claims 24, 25, 26, 27, 28, 29, 31, 32, 33, 34, 35, 36 are allowable.

Claims 21-23 are rejected.

Claims 30 and 37 are objected to.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.

The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
January 30, 2003



YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600